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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,651	07/28/2006	Kathleen Smith	PLP573	4890
23347 7590 11/23/2010 GLAXOSMITHKLINE GLOBAL PATENTS FIVE MOORE DR., PO BOX 13398 MAIL STOP: C.2111F RESEARCH TRIANGLE PARK, NC 27709-3398			EXAMINER ZEMAN, ROBERT A	
			ART UNIT 1645	PAPER NUMBER
			NOTIFICATION DATE 11/23/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/587,651

Applicant(s)

SMITH ET AL.

Examiner

ROBERT A. ZEMAN

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-9 and 11-44 is/are pending in the application.
- 4a) Of the above claim(s) 36-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-9 and 11-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed on 9-15-2010 is acknowledged. Claims 7-19 and 11-35 have been amended. Claims 1-6 and 10 have been canceled. Claims 7-9, 11-44 are pending. Claims 36-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 7-9 and 11-35 are currently under examination.

Claim Rejections Withdrawn

The rejection of claims 1-35 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of the amendment thereto.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "flanked by 10 at least a third and fourth marker sequences..." is withdrawn. Cancellation of said claim has rendered the rejection moot.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, for lacking antecedent basis for the limitations "third recombinant DNA sequences" and "fourth recombination cassettes" in lines 2-3 and 4 respectively is withdrawn. Cancellation of said claim has rendered the rejection moot.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, for lacking antecedent basis for the limitation "in I c)" in line 4 is withdrawn. Cancellation of said claim has rendered the rejection moot.

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase “homologous to a defined locus of the *S. cerevisiae* genome.” is withdrawn. Cancellation of said claim has rendered the rejection moot.

The rejection of claims 4, 7 and 8 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase “bearing in an allelic position...” is withdrawn in light of the cancellation of claim 4 and the amendment to claims 7 and 8.

The rejection of claims 1, 4-9, 13-14, 16-18 ,20-23, 27 and 30 under 35 U.S.C. 102(b) as being anticipated by Resnick et al. (U.S. Patent 6,391,642) is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 112, Deposit Requirement

Claims 7-9 and 11-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth in the previous Office action in the rejection of claims 10 and 15.

The copies of deposit certificates submitted on 9-15-2010 are acknowledged. However, the requirements set forth in 37 CFR 1.803 – 1.809 (see below) have not been met.

As outlined previously, it is apparent that the plasmids pMXy9 and pMXy12 and *Saccharomyces cerevisiae* strain MXy47 are required in order to practice the invention. The

deposit of biological organisms is considered by the Examiner to be necessary for the enablement of the current invention (see 37 CFR 1.808(a)).

If the deposit is made under terms of the Budapest Treaty, then an affidavit or declaration by Applicants or person(s) associated with the patent owner (assignee) who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty *and* that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit, or declaration by Applicants or person(s) associated with the patent owner (assignee) who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the following criteria have been met:

- 1) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;
- 2) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent; and
- 3) the deposits will be maintained for a term of at least thirty (30) years from the date of the deposit or for the enforceable life of the patent or for a period of at least five (5) years after the most recent request for the furnishing of a sample of the deposited material, whichever is longest; and
- 4) a viability statement in accordance with the provisions of 37 CFR 1.807; and
- 5) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 – 1.809 for additional explanation of these requirements.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 7-9 and 11-35 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps for essentially the reasons set forth in the previous Office action. See MPEP § 2172.01. The

omitted steps are: the specific method steps that need to be performed in order to detect the recombinant DNA sequences. Performing the recited steps would result in the detection of the generated DNA sequences in *Saccharomyces cerevisiae*.

New Grounds of Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 9 are rendered vague and indefinite by the use of the term "allelic position". It is unclear what is meant by said term as it is not specifically defined in the specification.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT A. ZEMAN whose telephone number is (571)272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Patricia Duffy can be reached on (571) 272-0855. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert A. Zeman/
Primary Examiner, Art Unit 1645
November 15, 2010